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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/077,283	02/14/2002	Matthias Rath	I1957/20	3317
26646	7590	02/25/2005	EXAMINER	
KENYON & KENYON ONE BROADWAY NEW YORK, NY 10004			MARX, IRENE	
			ART UNIT	PAPER NUMBER
			1651	
DATE MAILED: 02/25/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/077,283

Applicant(s)

RATH, MATTHIAS

Examiner

Irene Marx

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4-7 and 10-26 is/are pending in the application.
- 4a) Of the above claim(s) 4-7, 10-22 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 23-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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The amendment presented fails to comply with the **Revised Amendment Format 37 CFR 1.121**. Claims 1 and 23-24 are amended from “consisting essentially of” to “consisting of” or “consists of” without the appropriate indication of brackets, strike-throughs and/or underlining. Claim 25 is amended from “comprising” to “consists of” without the appropriate indication of brackets, strike-throughs and/or underlining. Correction is **required**.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/13/05 has been entered.

Claims 1 and 23-25 are being considered on the merits.

Claims 4-7, 10-22 and 26 are withdrawn from consideration as directed to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for the recited amounts/day as required in new claims 23-25 (See, e.g., Specification, page 6). There is no correlation between the recited ranges and “per day”. It is noted that “per day” is a dosage or administration limitation which inconsistent with a composition claim.

Moreover, no basis or support is found in the present specification for the composition claimed in claim 25 consisting of certain ingredients. The composition closest to that claimed

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appears to be disclosed at bridging paragraph between pages 10 and 11. However, the range of Lipoamide is 0.01 - 100 mg and it contains 0.01-10 mg calcium .

Response to Arguments

Applicant's arguments as they pertain to the above rejection have been fully considered but they are not deemed to be persuasive.

Applicant argues that the claimed range of each component administered daily is fully supported by the disclosure of the current application, referring to Specification, page 5 lines 29 to 34 and Table 6.) However, the disclosure cited does not pertain with any specificity to the invention as claimed. It is noted that Table 6 has specific amounts rather than ranges. Also the components do not correspond to any of the claim designated inventions.

Please see *Gentry Gallery v. Berkline* 45 U.S.P.Q.2d 1498 for a discussion related to broadening the claimed invention without support in the as-filed specification. Please see *PurduePharma v. Faulding* 56 U.S.P.Q.2d 1481 for a discussion related to a failure to describe a claimed generic concept in the narrative portion of the specification, but rather basing support on limitations in examples.

In addition, as noted supra, "per day" is a dosage or administration limitation which inconsistent with a composition claim.

Therefore the rejection is deemed proper and it is adhered to.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 23-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 23-25 are vague, indefinite and confusing in that the compositions "consists of" two or more components..., respectively specified ingredients, and "is administered as tablets, etc.". To begin with, the claims are inconsistent in the recitation of "consists of" while appearing to add ingredients to provide tablets, pills, suppositories, etc.. In addition, the claims are improper in having the active step "is administered as" in a composition claim. The only

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type of composition claim that may include process steps is a product-by-process claim, which is not the case here.

Claims 23-25 are confusing in that there appears to be a missing linker before “is administered”, such as “and”.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by The Merck Index. See, entry 1701, which consists of calcium and citrate; entry 5699 which consists of magnesium and citrate; entry 1688 which consists of calcium and ascorbic acid.

It is noted that the reference does not teach that the composition can be used for improving bioenergy metabolism, however, the intended use of the composition does not distinguish the composition since such undisclosed use is inherent in the disclosed composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus, the intended use is not limiting. “The claiming of a new use . . . which is inherently present in the prior art does not necessarily make the claim patentable.” *In re Best*, 195 USPQ 430, 433 (CCPA 1977). When applicant claims a “composition in terms of function . . . and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the Examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection” (MPEP 2112).

Regarding the administration step, it is noted that such a step is improper in a composition claim, as noted *supra*.

Claim 1 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Sigma Catalog See, e.g. page 772, for a composition consisting of calcium and pantothenic acid or page 950 for a composition consisting of succinate and calcium.

It is noted that the reference does not teach that the composition can be used for improving bioenergy metabolism, however, the intended use of the composition does not distinguish the composition since such undisclosed use is inherent in the disclosed composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus, the intended use is not limiting. "The claiming of a new use . . . which is inherently present in the prior art does not necessarily make the claim patentable." *In re Best*, 195 USPQ 430, 433 (CCPA 1977). When applicant claims a "composition in terms of function . . . and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the Examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection" (MPEP 2112).

Regarding the administration step, it is noted that such a step is improper in a composition claim, as noted *supra*.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mothernature.com taken with Whole Health Discount Center. The claims are directed to a composition consisting of two or more chemical substances from a list that includes citrate and calcium.

Each of Mothernature.com or Whole Health Discount Center teaches a composition consisting essentially of calcium and magnesium citrate for oral administration. It is noted that the reference does not teach that the composition can be used for improving bioenergy metabolism, however, the intended use of the composition does not distinguish the composition since such undisclosed use is inherent in the disclosed composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus, the intended use is not limiting. "The claiming of a new use . . . which is inherently present in the prior art does not necessarily make the claim patentable." *In re Best*, 195 USPQ 430, 433 (CCPA 1977). When applicant claims a "composition in terms of function . . . and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the Examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection" (MPEP 2112).

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The references differs from the invention as claimed in containing ingredients other than the compounds *per se*. However, the provision of chemical compounds as nutritional supplements such as vitamins and calcium supplements is old and well known in the art, and applicant has not demonstrated that administration of at least two ingredients from a list in any amount as claimed provides unexpected results.

Regarding the administration step, it is noted that such a step is improper in a composition claim, as noted *supra*.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the compositions of Mothernature.com or Whole Health Discount Center if necessary, by excluding other ingredients, such as vitamin D.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments as they pertain to the above rejection have been fully considered but they are not deemed to be persuasive.

Applicant states that the amounts in the references are outside the claimed range of this invention. However, there is no indication for the reasoning behind this allegation. The statement is particularly puzzling in the absence of any amounts in claim 1.

Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Irene Marx
Primary Examiner
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